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APPLICATION NO.	FILING DATE	FIRST-NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,211	10/30/2006	Bakulesh Mafatlal Khamar	574152000400	9175

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/565,211

Applicant(s)

KHAMAR, BAKULESH MAFATLAL

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-47 is/are rejected.
- 7) ☒ Claim(s) 22,28-32,34 and 44-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Preliminary Amendment, received 20 January 2006, is acknowledged. Claims 1-21 have been canceled. New claims 22-47 have been added.
2. Claims 22-47 are pending and under consideration.

Specification

3. The disclosure is objected to because of the following informalities:

Throughout the entire application, the bacterium is listed as "Mycobacterium w", "mycobacterium W", and "mycobacterium w". Use only one designation. Likewise the abbreviation for the bacterium is listed as "M_w" and "Mw". Use only one designation.

Page 1, title, line 2, "COMPRISES" should be "COMPRISED"; line 3, "ASTHAMA" should be "ASTHMA"; line 5, "Asthma" should be "asthma"; line 12, "is a ill" should be "is an ill", "lung disease" should be "lung diseases"; line 13, "disorder" should be "disorders"; line 15, delete on of the (; line 24, "no." should be "number"; line 26, "Chronis" should be "Chronic"; line 26, "precipitates" should be "precipitate"; line 27, "is are" should be "are", "the no." should be "the number"; line 32, "exacerbations" should be "exacerbation".

Page 2, line 4, "thickning" should be "thickening"; line 13, "characterised" should be "characterized"; line 18, "diffuculty" should be "difficulty"; line 22, "dyspnoea" should be "dyspnea"; line 24, "Asthma" should be "asthma"; line 28, "characterised" should be "characterized"; line 29, what is "felling".

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Page 3, line 1, "bronchodilators" should be "bronchodilator"; line 3, "comprises of use of" should be "comprises the use of"; line 4, "Corticosteriodsand leucotrein Antagonists" should be "corticosteroids and leucotriene antagonists"; line 6, "Corticosteriods" should be "Corticosteroids"; line 11, "servere" should be "severe"; line 18, "somke" should be "smoke"; line 30, "The dependent on drugs" should be "The dependence on drugs".

Page 4, line 2, "According to present" should be "According to the present"; line 13, "in on respect" should be "in one respect"; line 23, there should be an "and" immediately preceding "M. paratuberculosis".

Page 5, line 5, "attacks bronchial" should be "attacks of bronchial".

Page 8, lines 11, 12, 15, "middle brook" should be "Middlebrook".

Page 9, line 12, "palletisation" should be "pelletization"; lines 15, 19, "pallet" should be "pellet"; line 25, "thiomesol" should be "thiomerasol".

Page 10, line 5, "pasturisation" should be "pasteurization"; line 9, what is meant by "before after filling"?; line 16, what is meant by "infected to Balb/c"?

Page 11, line 13, "extration" should be "extraction".

Page 12, line 3, "liticase" should be "lyticase".

Page 13, line 7, what is meant by "inspite of that she"; line 12, "asymnptomatic" should be "asymptomatic"; line 14, "patient is a taking" should be "a patient is taking".

Page 14, lines 13-16, the sentence beginning "In a group" is unclear; line 28, "The no. of" should be "The number of".

Appropriate correction is required.

Claim Objections

4. Claim 22 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

5. Claim 28 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

6. Claim 29 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

7. Claim 30 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

8. Claim 31 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

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9. Claim 32 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

10. Claim 34 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

11. Claim 44 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

12. Claim 45 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

13. Claim 46 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

14. Claim 47 is objected to because of the following informalities: "mycobacterium w" should be "Mycobacterium w" to be consistent with the rest of the application. Appropriate correction is required.

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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16. Claim 22-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - The claims are drawn to methods of treating/managing/preventing obstructive lung disease comprising administration to a patient a pharmaceutical composition comprising an effective amount of Mycobacterium w prepared by cell disruption, solvent extraction, or enzymatic extraction.

The amount of direction/guidance/examples present - The instant specification in its present form, while reciting various preparations of Mycobacterium w, does not specify which of the types was actually utilized nor how much of the composition was administered. Therefore, there is insufficient information to enable the instant claims. The required information to support the instant claims, at a minimum, would be the actual composition administered to the patients (whole cells, disrupted cells, cell fractions, etc), the dosage administered, the route of administration, and the frequency of administration.

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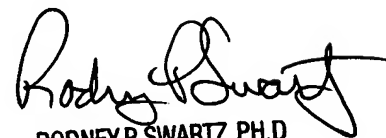
Conclusion

17. No claims are allowed.
18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER
Art Unit 1645

March 3, 2007